

REMARKS

Applicants have carefully reviewed and considered the Office Action mailed on February 16, 2005 and the documents cited therewith.

Claims 1, 4, 7-22, and 25 are pending.

Objection to Claims

Claims 1 and 25 were objected to for recitation of the phrase *consists essentially of*. The Examiner alleged that the phrase is improper and suggested that *consisting essentially of* or *comprising* are proper. The Examiner stated she has interpreted the phrase objected to as *comprising*. This objection is respectfully traversed.

The Examiner apparently is confusing transitional phrases, which follow the preamble immediately, with phrases that appear in the body of the claim. When the phrase *consists of* appears in a clause in the body of a claim, rather than immediately following the preamble, it is proper, and limits only the element set forth in that clause; other elements are not excluded from the claim as a whole. MPEP 2111.03, page 2100-52, second column.

Applicant's claims 1 and 25 recite *consists essentially of* in a clause in the body of the claim. Applicant submits that if *consists of* is proper in such a clause, then *consists essentially of* is proper as well. Withdrawal of this objection is respectfully requested.

Rejection Under 35 U.S.C. § 102(b)

Claims 1, 22, and 25 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by the Atrisone[®] product sheet, which the Examiner has alleged was copyrighted in 1995 by Doctor's Guide Publishing Limited. This rejection is respectfully traversed.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ 2d 1913, 1920 (Fed. Cir. 1989). To constitute anticipation, the claimed subject matter must be identically disclosed in the prior art. *In re Arkley*, 172 U.S.P.Q. 524 at 526 (C.C.P.A. 1972). For anticipation, there must be no difference

between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the art. *Scripps Clinic & Res. Found. v. Genentech, Inc.*, 927 F.2d 1565, 18 USPQ2d 101 (Fed. Cir. 1991). To overcome the defense of anticipation, “it is only necessary for the patentee to show some tangible difference between the invention and the prior art.” *Del Mar Engineering Lab v. Physio-Tronics, Inc.*, 642 F.2d 1167, 1172, (9th Cir. 1981).

Moreover, an anticipation rejection that is based on inherency must be supported by factual and technical grounds establishing that the inherent feature must flow as a necessary conclusion, not simply a possible conclusion, from the teaching of the cited art. *Ex parte Levy*, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Int. 1990); *In re Oelrich*, 666 F.2d 578, 212 U.S.P.Q. 323, 326 (C.C.P.A. 1981).

Applicant submits that the Atrisone[®] product sheet (Doctor’s Guide Global Edition) is not prior art even if it bears a 1995 copyright date. The disclosure of Phase III clinical trials for Atrisone[®] (Dapsone topical gel), which is Applicant’s invention, was dated March 29, 2002, which is after Applicant’s filing date. Applicant encloses a copy of the cited Doctor’s Guide Global Edition article, but printed directly from the website using the printable version of the article, and draws the Examiner’s attention to the first page, 4th line below the line of dashes for the disclosure date of March 29, 2002.

Applicant further submits that it is impossible to copyright an article with a date that is years before the disclosure of the subject of the article and years before the U.S. Food and Drug Administration (FDA) approved the subject of the article. This is analogous to copyrighting a book before it is written or before its subject is even contemplated by the author. The FDA approved topical Dapsone for treatment of inflammatory acne only in 2004. Topical Dapsone treatment was not approved in 1995, and such treatment was non-existent in 1995. The 1995 copyright date could conceivably apply to the website itself or to aspects of the website, but a 1995 copyright date certainly does not apply to the contents of an article disclosed in the website in 2002. For additional evidence in this regard, the Examiner’s attention is respectfully drawn to page 3 of an identical article from the Doctor’s Guide Channels website, which indicates that the contents are copyrighted under various copyrights dated from 1995-2005. In addition, the printable version of the Doctor’s Guide Channels article (showing the disclosure date as March

29, 2002), is identical to the printable version of the Doctor's Guide Global Edition article and has the same URL thereof.

Withdrawal of this rejection is respectfully requested.

Rejections Under 35 U.S.C. § 103(a)

Claims 4, 7, 13, 14, 20, and 21 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Atrisone[®] product sheet in view of U.S. Patent 6,060,085 or the Atrisone[®] product sheet in view of U.S. Patent 5,863,560. This rejection is respectfully traversed.

As Applicant has pointed out above, the Atrisone[®] product sheet is not prior art. Therefore, any combination rejection under § 103(a) that employs the Atrisone[®] product sheet as a primary reference must fail. Withdrawal of this rejection is respectfully requested.

Claims 8-12 and 15-19 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Atrisone and U.S. Patent 6,060,085 or Atrisone and U.S. Patent 5,863,560 in view of U.S. Patent 6,200,964 to Singleton et al. Applicant presumes that Atrisone cited in the rejection is the Atrisone[®] product sheet cited supra. Clarification is requested.

The Examiner recognizes that creams, lotions, suspensions, ointments, or sprays are not disclosed in the Atrisone[®] product sheet, in U.S. Patent 6,060,085, or in U.S. Patent 5,863,560. She therefore cited Singleton et al. for its disclosure of spray, cream, lotion, suspension, or gel formulations containing salicylic acid for the treatment of acne. Furthermore, she alleged the obviousness of preparing Dapsone containing dissolved and microparticulate fractions in the form of spray, lotion, cream, or ointment in view of the disclosure of Singleton et al. so as to reduce the number of inflammatory or non-inflammatory acne lesions. This rejection is respectfully traversed.

As Applicant has pointed out above, the Atrisone[®] product sheet is not prior art. This leaves a rejection reading U.S. Patent 6,060,085 (Osborne II) or U.S. Patent 5,863,560 (Osborne I) in view of U.S. Patent 6,200,964 to Singleton et al. Since Osborne II is a continuation of Osborne I, the disclosures thereof are identical.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation either in the cited references themselves or in the

knowledge generally available to an art worker, to modify the reference or to combine reference teachings so as to arrive at the claimed method. Second, the art must provide a reasonable expectation of success. Finally, the prior art reference must teach or suggest all the claim limitations (M.P.E.P. § 2143). The teaching or suggestion to arrive at the claimed method and the reasonable expectation of success must both be found in the prior art, not in Applicant's disclosure (M.P.E.P. § 2143 citing with favor, *In re Vaeck*, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991)).

Applicant reiterates his earlier argument, filed November 29, 2004, that the Osborne patents do not disclose that Dapsone can be used to treat non-inflammatory acne (i.e., blackheads), as is currently claimed. The Osborne patents indicate that Dapsone is an anti-microbial agent having anti-inflammatory properties (col. 3, lines 9-11; col. 4, line 66-col. 5, line 1 of Osborne I). The Osborne patents focus upon the anti-inflammatory and anti-microbial properties of Dapsone for treatment of acne (col. 7, line 65-col. 8, line 9 of Osborne I). Dapsone is an anti-leprosy drug that requires frequent blood counts and laboratory monitoring. Its formulations would be available only by prescription, not over the counter. Thus, a physician reading the Osborne patents descriptions would understand that the kind of acne being treated therein is inflammatory acne caused by a microbial infection and not non-inflammatory acne as in Applicant's claims. Singleton et al. does not remedy this deficiency. Accordingly, all of the claim elements are not disclosed by the cited documents.

Moreover, that person of skill would know that other remedies, and not anti-microbials, are useful for the treatment of blackheads. Accordingly, the routineer would have had no motivation to use the Osborne disclosures for treating non-inflammatory acne or for reducing a number of non-inflammatory lesions. Nor would the routineer have had an expectation of success in using the Osborne disclosures for treating non-inflammatory acne or for reducing a number of non-inflammatory lesions. Such motivation and expectation of success come only from Applicant's disclosure. Therefore, the Examiner has not established a *prima facie* case of obviousness. Withdrawal of this rejection is respectfully requested.

RESPONSE UNDER 37 CFR § 1.111

Serial Number: 10/081,050

Filing Date: February 20, 2002

Title: Topical Dapsone for the Treatment of Acne

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Dkt: 1195.346US1

Doc. No.: 622727

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at 703-239-9592 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Mail Stop Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the 6th day of April, 2005.

Name

Signature